Proposed Re-evaluation Decision PRVD2010-07

Para-dichlorobenzene

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Overview

What Is the Proposed Re-evaluation Decision?

After a re-evaluation of para-dichlorobenzene, Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is proposing continued registration for the sale and use of products containing para-dichlorobenzene in Canada.

An evaluation of available scientific information found that pesticide products containing para-dichlorobenzene do not present unacceptable risks to human health or the environment when used according to label directions. As a condition of the continued registration of para-dichlorobenzene uses, new risk-reduction measures must be implemented for all products. Additional data are being requested as a result of this re-evaluation.

This proposal affects all pesticide end-use products containing para-dichlorobenzene registered in Canada. Once the final re-evaluation decision is made, the registrants will be instructed on how to address any new requirements.

This Proposed Re-evaluation Decision is a consultation document[1] that summarizes the science evaluation for para-dichlorobenzene and presents the reasons for the proposed re-evaluation decision. It also proposes additional risk-reduction measures to reduce the potential of accidental ingestion of mothballs.

The information is presented in two parts. The Overview describes the regulatory process and key points of the evaluation, while the Science Evaluation provides detailed technical information on the assessment of para-dichlorobenzene.

The PMRA will accept written comments on this proposal up to 45 days from the date of publication of this document. Please forward all comments to Publications (please see contact information indicated on the cover page of this document).

What Does Health Canada Consider When Making a Re-evaluation Decision?

Para-dichlorobenzene as a pest control product is part of the PMRA's current pesticide re-evaluation program. This program considers potential risks, as well as value, of pesticide products to ensure they meet modern standards established to protect human health and the environment. Regulatory Directive DIR2001-03, *PMRA Re-evaluation Program*, presents the details of the re-evaluation activities.

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1 "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

Para-dichlorobenzene is also used as a deodorant, and has been assessed under the *Canadian Environmental Protection Act* (CEPA) in 1993 and 2003.

In the US, pesticide uses of para-dichlorobenzene have undergone re-evaluation as part of the Environmental Protection Agency Program, and a Reregistration Eligibility Decision (RED) document was published in December 2008. Based on the health and environmental risk assessments published in the 2008 RED, the USEPA concluded that para-dichlorobenzene was eligible for registration provided risk-reduction measures were adopted. The USEPA RED was found to cover the science areas that are necessary for the Canadian re-evaluation of para-dichlorobenzene pest control uses, and to address all formulation types and uses of para-dichlorobenzene in Canada.

The USEPA RED and the Canadian CEPA assessments were used as a basis for the proposed Canadian re-evaluation decision.

In this decision, the PMRA has also taken into consideration the Canadian specific chemistry of registered pest control products as well as the federal Toxic Substances Management Policy (TSMP).

For more details on the information presented in this overview, please refer to the Science Evaluation section of this consultation document.

What Is Para-dichlorobenzene?

When used as a pest control product, para-dichlorobenzene is an insecticide that is used to control moth and moth larvae which are destructive to textiles made of natural fibres. Mothballs are placed by hand by home owners in chest boxes or airtight trunks where clothing is stored.

Health Considerations

Can Approved Uses of Para-Dichlorobenzene Affect Human Health?

Para-dichlorobenzene is unlikely to affect your health when used according to the revised label directions.

Exposure to para-dichlorobenzene could occur during placement of mothballs by home owners, after placement from inhabiting indoor treated areas with para-dichlorobenzene, and from accidental ingestion of mothballs by children.

The PMRA considers two key factors when assessing health risks: the levels at which no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (e.g. children and nursing mothers).

The 2008 USEPA RED covers the aspects of human health risk assessment that are necessary for the Canadian re-evaluation of para-dichlorobenzene pesticidial uses, and it addresses all para-dichlorobenzene formulation types and uses registered in Canada. The USEPA concluded that para-dichlorobenzene was unlikely to affect human health provided that risk-reduction measures were implemented. These conclusions apply to the Canadian situation, and equivalent risk-reduction measures are required.

The CEPA assessment estimated the potential risk to the Canadian population from exposure to para-dichlorobenzene based on measured concentrations in homes in Canada. Although this assessment cannot be directly related to the use of pest control products since there are multiple sources of para-dichlorobenzene, the overall conclusion was taken into consideration in this re-evaluation. The CEPA assessment has concluded that para-dichlorobenzene is not entering the environment in quantities or under conditions that may constitute a danger in Canada to human life or health. No additional mitigation measures were proposed.

The PMRA concluded that para-dichlorobenzene was unlikely to affect human health provided that risk-reduction measures were implemented.

Environmental Considerations

What Happens When Para-Dichlorobenzene Is Introduced Into the Environment?

Para-dichlorobenzene is unlikely to affect non-target organisms when used according to the label directions.

According to label directions, mothballs are to be placed exclusively indoors and no environmental exposure is expected to result from the use of para-dichlorobenzene as a pest control product. Furthermore, the 2003 CEPA assessment concluded that para-dichlorobenzene is not entering the environment in quantities or under conditions that may be harmful to the environment.

Measures to Minimize Potential Risk

As a result of the re-evaluation of para-dichlorobenzene, the PMRA is proposing further risk-reduction measures.

- Modification of packaging to reduce the potential for accidental ingestion by toddlers.
- Add the statement: "For indoor use only" to clarify that outdoor uses are not permitted.
- Add the statement: "Do not place in areas accessible to children".

What Additional Scientific Information Is Required?

Data are required as a condition of continued registration under Section 12 of the *Pest Control Products Act*. The registrants of this active ingredient must provide these data or an acceptable scientific rationale to the PMRA within the timeline specified in the decision letter. Appendix I lists all data requirements.

Next Steps

Before making a final re-evaluation decision on para-dichlorobenzene, the PMRA will consider all comments received from the public in response to this consultation document. The PMRA will then publish a Re-evaluation Decision[2] document that will include the decision, the reasons for it, a summary of comments received on the proposed decision and the PMRA's response to these comments.

2 "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

Science Evaluation

1.0 Introduction

Para-dichlorobenzene is an insecticide used for control of moth and moth larvae which are destructive to textiles made of natural fibres.

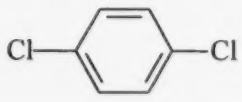
Following the re-evaluation announcement for para-dichlorobenzene, the registrant of the technical grade active ingredient in Canada indicated that they intended to provide continued support for all uses included on the labels of domestic end-use products in Canada.

The PMRA used recent assessments of para-dichlorobenzene from the United States Environmental Protection Agency (USEPA), as well as the assessments for para-dichlorobenzene under the *Canadian Environmental Protection Act* (CEPA).

Health Canada and Environment Canada's Assessments for para-dichlorobenzene are available at www.ec.gc.ca/substances/ese/eng/psap/PSL1_1_4_dichlorobenzene.cfm. The USEPA RED document for para-dichlorobenzene, dated December 29, 2008, other information on the regulatory status of para-dichlorobenzene in the United States can be found on the USEPA Pesticide Registration Status page at www.epa.gov/pesticides/reregistration/status.htm.

2.0 The Technical Grade Active Ingredient, Its Properties and Uses

2.1 Identity of the Technical Grade Active Ingredient

Common name	Not required by ISO
Function	Insecticide
Chemical family	chlorinated benzene
Chemical name	
1 **International Union of Pure and Applied Chemistry (IUPAC)**	p-dichlorobenzene
2 **Chemical Abstracts Service (CAS)**	1,4-dichlorobenzene
CAS Registry Number	106-46-7
Molecular formula	$C_6H_4Cl_2$
Structural formula	

Molecular weight	147
Purity of the technical grade active ingredient	99.9% minimum
Registration Number	21001

Identity of relevant impurities of human health or environmental concern:

It is not possible to assess the presence of impurities of human health or environmental concern as identified in the Canada Gazette, Part II, Vol. 142, No. 13, SI/2008-67 (2008-06-25), including TSMP Track 1 substances, in the product as a detailed manufacturing process is not available.

2.2 Physical and Chemical Properties of the Technical Grade Active Ingredient

Property	Result
Vapour pressure at 25°C	170 Pa
UV–visible spectrum	λ_{max} = 265 nm
Solubility in water at 25°C	80 mg/L
***n*-Octanol–water partition coefficient**	Log K_{ow} = 3.44
Dissociation constant	Not applicable

2.3 Comparison of Use Patterns in Canada and the United States

Para-dichlorobenzene is an insecticide used for control of moths and moth larvae. The registered domestic end use products are formulated as crystals, solid, pellet, blocks, balls and cakes. It is used indoors, in chest boxes or airtight trunks holding clothing and is applied by hand with an application rate of up to 300 g a.i./m^3.

All current uses are being supported by the registrant(s) and were, therefore, considered in the re-evaluation of para-dichlorobenzene. Appendix II lists all para-dichlorobenzene products that are registered as of September 23, 2009, under the authority of the *Pest Control Products Act*.

3.0 Impact on Human Health and the Environment

3.1 Human Health

3.1.1 Contaminants and Degradates/Metabolites of Toxicological Concern

Based on limited data available, the manufacturing process may yield contaminants of concern. Therefore, an analysis for impurities of human health and/or environmental concern is required.

3.1.2 Health Canada/Environment Canada Risk Assessment

Para-dichlorobenzene can be used as a pesticide as well as a deodorant. The *Canadian Environmental Protection Act* (CEPA) requires the Minister of the Environment and the Minister of Health to conduct assessments of substances that may be harmful to the environment or human health. In 1993, Healthy Environment and Consumer Safety Branch of Health Canada conducted an assessment of para-dichlorobenzene under CEPA. The published assessment "1,4-Dichlorobenzene (Priority Substance List Assessment Report)" reported:

- The total daily intake of 1,4-dichlorobenzene for various age groups in the Canadian population was estimated to range from 0.1 to 2.1 µg/kg bw. These estimated average daily intakes were less (by 37 to 780 times) than the tolerable daily intake (TDI), which was derived on the basis of the results of studies by the route of exposure which is most important for the general population (i.e., inhalation).

The assessment concluded that para-dichlorobenzene was not entering the environment in quantities or under conditions that may constitute a danger to the environment on which human life depends, or to human life or health.

3.1.3 USEPA health risk assessment:

The USEPA has completed a human health and ecological risk assessment of pesticide uses under their reregistration program. A risk management decision was published in a 2008 RED, and para-dichlorobenzene was found eligible for reregistration as a pesticide provided that the recommended mitigation measures are implemented.

The USEPA health risk assessment included an estimate of potential risk in residential settings a) during application by homeowners (via dermal), b) post-application from inhabiting indoor areas previously treated with para-dichlorobenzene (via inhalation), c) from episodic ingestion by toddlers, and d) via drinking water. The risk assessments were as follows.

a) During application:
A quantitative assessment was conducted to estimate the risk from dermal exposure for homeowners applying para-dichlorobenzene indoors and outdoors in residential settings. The estimated margins of exposure (MOE), ranging from 33 000 to 224 000, were greater than 100 and therefore, below the EPA's level of concern. Residential handler inhalation exposure

was not assessed because appropriate data were not available for this scenario. However, it was determined that the short-term post-application inhalation assessment would be protective for residential handler inhalation exposure, since measured concentrations of para-dichlorobenzene would likely be greater due to the time allotted in the exposure study for product accumulation in enclosed treated areas.

b) Post-application indoor:

Post-application dermal exposure was not assessed as no dermal contact was expected due to the complete sublimation (dissipation) of para-dichlorobenzene mothballs. In the 2008 RED, post-application exposure from accessing and inhabiting treated areas was considered to be short-, intermediate- and long-term in duration. Acceptable MOEs, ranging from 160 to 1650, were reported. They were above the target MOE of 100.

In 2007, the USEPA Cancer Assessment Review Committee (CARC) classified para-dichlorobenzene as "Not Likely to be Carcinogenic to Humans" based on evidence that a non-mutagenic mode-of-action involving mitogenesis was established for para-dichlorobenzene.

c) Mothball ingestion by children:

There is a potential for accidental ingestion of mothballs by children. Ingestion of mothballs is not considered to be a routine behaviour, but rather an episodic event. Since no endpoint attributable to an acute oral exposure was identified, episodic ingestion of para-dichlorobenzene was not assessed in the 2008 RED. In order to reduce the potential for accidental mothball ingestion by children, the PMRA recommends that registrants modify the packaging of mothballs (Appendix III).

d) Exposure From Food and Drinking Water

In the US, there are no registered food uses, and no outdoor uses, and drinking water exposure is not anticipated. Therefore, the USEPA did not conduct a dietary risk assessment. Similarly, in Canada, there are no registered food uses and no outdoor uses and hence, the USEPA assessment is considered applicable to the Canadian situation.

3.2 Environment

Based on the fact that there are only indoor uses of para-dichlorobenzene registered in the US, no ecological risk assessment was conducted by the USEPA. There are no outdoor uses of para-dichlorobenzene registered in Canada.

Environment Canada conducted an assessment of para-dichlorobenzene under the *Canadian Environmental Protection Act* (CEPA) in 1993 and a following up assessment in 2003. The assessments determined that concentrations of para-dichlorobenzene present in Canadian air, surface waters, sediment and soils were not likely to cause adverse effects on non target organisms, including aquatic biota, wildlife population of benthic and soil-dwelling species. Para-dichlorobenzene is not entering the environment in a quantity or concentration or under

conditions that have or may have an immediate or long-term harmful effect on the environment or its biological diversity. Therefore, para-dichlorobenzene is not considered as "toxic" as defined under Paragraph 64(a) of CEPA 1999.

3.3 Canadian Specific Considerations

3.3.1 Toxic Substances Management Policy Considerations

The Toxic Substances Management Policy (TSMP) is a federal government policy developed to provide direction on the management of substances of concern that are released into the environment. The TSMP calls for the virtual elimination of Track 1 substances (those that meet all four criteria outlined in the policy, i.e., CEPA-toxic or equivalent, predominantly anthropogenic, persistent and bio-accumulative).

During the reevaluation process, para-dichlorobenzene was assessed in accordance with the PMRA Regulatory Directive DIR99-03, *The Pest Management Regulatory Agency's Strategy for Implementing the Toxic Substances Management Policy,* and evaluated against the Track 1 criteria for persistence and bioaccumulation. In order for para-dichlorobenzene or its transformation products to meet Track 1 criteria, the criteria for both bioaccumulation and persistence (in one media) must be met. The PMRA has reached the following conclusion:

- para-dichlorobenzene does not meet Track 1 criteria, and is not considered a Track 1 substance. The table below shows a comparison of para-dichlorobenzene's fate characteristics with Track 1 criteria.

Toxic Substances Management Policy Considerations – Comparison to TSMP Track 1 Criteria

TSMP Track 1 Criteria	TSMP Track 1 Criterion Value	Para-dichlorobenzene Fate Characteristic Value	Criterion Met
Bioaccumulation	Log $K_{ow} \geq 5$	3.44	no

3.3.2 Formulants of Health or Environmental Concern

The use of formulants in registered pest control products is assessed on an ongoing basis through PMRA formulant initiatives and Regulatory Directive DIR2006-02, *Formulants Policy and Implementation Guidance Document.*

4.0 Incident reports

Since April 26, 2007, registrants have been required by law to report incidents, including adverse effects to health and the environment, to the PMRA within a set time frame. The PMRA examines incident reports and, where there are reasonable grounds to suggest that the health and environmental risks of the pesticide are no longer acceptable, appropriate measures are taken, ranging from minor label changes to discontinuation of the product.

There were no incident reports submitted for para-dichlorobenzene as of September 23, 2009.

5.0 OECD Status of Para-dichlorobenzene

Canada is part of the Organisation for Economic Co-operation and Development (OECD), which groups 30 member countries and provides governments with a setting in which to discuss, develop and perfect economic and social policies. They compare experiences, share information and analyses, seek answers to common problems, and work to co-ordinate domestic and international policies to allow for consistency in practices across nations.

Para-dichlorobenzene has been restricted in Sweden since Jan 1, 1990. In Australia, para-dichlorobenzene is registered for control of clothes moths in domestic, commercial and industrial situations.

The United States, also an OECD member, has assessed the pesticidial use of para-dichlorobenzene in 2008 and concluded that using para-dichlorobenzene does not result in unreasonable adverse effects to human health or the environment provided the risk mitigation measures recommended in the RED document were implemented.

As described above, the USEPA environmental and human health risk conclusions to be relevant to the pesticidial use of para-dichlorobenzene in Canada.

6.0 Proposed Re-evaluation Decision

The PMRA has determined that para-dichlorobenzene is acceptable for continued registration with the implementation of the proposed risk-reduction measures. These measures are required to further protect human health. The labels of Canadian end-use product must be amended to include the label statements as listed in Appendix III. A submission to implement label revisions will be required within 90 days of finalization of the re-evaluation decision. The registrant of the technical grade active ingredient is required to submit data as a condition of continued registration under Section 12 of the *Pest Control Products Act*. Appendix I lists the data requirements.

7.0 Supporting Documentation

PMRA documents, such as Regulatory Directive DIR2001-03, and DACO tables can be found on our website at www.healthcanada.gc.ca/pmra. PMRA documents are also available through the Pest Management Information Service. Phone: 1-800-267-6315 within Canada or 1-613-736-3799 outside Canada (long distance charges apply); fax: 613-736-3798; e-mail: pmra.infoserv@hc-sc.gc.ca.

Health Canada and Environment Canada's assessments for para-dichlorobenzene are available at www.ec.gc.ca/substances/ese/eng/psap/PSL1_1_4_dichlorobenzene.cfm.

The federal TSMP is available through Environment Canada's website at www.ec.gc.ca/toxics.

The USEPA RED document for para-dichlorobenzene is available on the USEPA Pesticide Registration Status page at www.epa.gov/pesticides/reregistration/status.htm.

List of Abbreviations

µg	microgram
a.i.	active ingredient
bw	body weight
CAS	Chemical Abstracts Service
g	gram(s)
IUPAC	International Union of Pure and Applied Chemistry
kg	kilogram(s)
K_{ow}	*n*-octanol–water partition coefficient
m^3	metre(s) cubed
mg	milligram(s)
MOE	margin of exposure
OECD	Organisation for Economic Co-operation and Development
PCPA	*Pest Control Products Act*
PMRA	Pest Management Regulatory Agency
ppm	parts per million
PRVD	Proposed Re-evaluation Decision
RED	Reregistration Eligibility Decision
RVD	Re-evaluation Decision
TGAI	technical grade active ingredient
TSMP	Toxic Substances Management Policy
USEPA	United States Environmental Protection Agency
UV	ultraviolet

Appendix I Additional Data Requirements

DACO 2.11.3 Detailed Production Process Description

Detailed information on the manufacturing process of the TGAI must be provided.

DACO2.13.4 Impurities of Toxicological Concern

Recent analytical data from at least five recent batches of the TGAI must be provided for tetrachlorobenzene, pentachlorobenzene and hexachlorobenzene, from a GLP-compliant or government accredited laboratory. The analytical method(s) used must utilize the lowest practical limits of quantitation and fully specified, either by reference to a standard method or by inclusion of a detailed description together with validation data.

Appendix II Registered Products Containing Para-dichlorobenzene as of September 23, 2009 (exclude discontinued products)

Registration Number	Marketing Class	Registrant	Product Name	Formulation Type	Guarantee (%)
21001	T	Recochem Inc.	Recochem Para-Zene Technical Paradichlorobenzene	solid	99.9
2528	D	Recochem Inc.	Recochem Para-Zene Moth Crystals	pellet	99.9
17055	D	Recochem Inc.	Cedar Scented Moth Balls	solid	99
21002	D	Recochem Inc.	Para-Zene Moth Rid	tablet	99
2528-1	D	Home Hardware Stores Ltd.	Home Moth Crystals	pellet	99.9
17055-1	D	Home Hardware Stores Ltd.	Home Cedar Scented Moth Balls	solid	99
2994	D	Produits Cadillac Ltée	Cadillac Moth Crystals	solid	99.9
19005	D	Produits Cadillac Ltée	Cadillac Moth Killer Perfumed Block	solid	98
27624	D	Distributions Multi-Pro Inc.	Multi-Pro Moth Crystals	solid	99

Appendix III Additional Mitigation Measures Required for Products Containing Para-Dichlorobenzene

1) Packaging amendments:

A) Registrants are required to modify the packaging of end-use products to mitigate the risk of accidental ingestion of mothballs by children. Loose mothballs should no longer be sold in Canada, and registrants are required to submit a proposal for packaging/formulation options which would discourage children from eating the product (e.g., para-dichlorobenzene formulated as blocks or cakes, packaged individually in sachets). Additional label language is also required to ensure that para-dichlorobenzene products are not applied to areas accessible to children.

Registrants are required to modify the packaging of mothballs and flakes to minimize the release of vapours while para-dichlorobenzene products are in storage. Submission of a proposal for packaging options is required, this may include use of a re-sealable hermetically closed container, and reduction of the number of mothballs/amount of flakes per product.

2) Label amendments

The following statement must be added to the **PRIMARY DISPLAY PANEL**

For indoor use only.

The following statement must be added in a section entitled **DIRECTIONS FOR USE**.

Do not place in areas accessible to children.

A submission to request label revisions will be required within 90 days of finalization of the re-evaluation decision.

References

Studies considered in the Chemistry Assessment

LIST OF STUDIES/INFORMATION SUBMITTED BY REGISTRANT

PMRA Document Number: 1448800
Reference: Information migrated from TGAI Chemistry paper files ("Brown" Files) PDB-NAI-1, Data Numbering Code: 2.99

PMRA Document Number: 1722989
Reference: PDCB Flakes production, Data Numbering Code: 2.11

PMRA Document Number: 1722990
Reference: 2009, Paradichlorobenzene Flaking Operation, Data Numbering Code: 2.11

PMRA Document Number: 1722992
Reference: 2008, Certificat of Analysis, Data Numbering Code: 2.13.3

PMRA Document Number: 1722993
Reference: 2008, Certificat of Analysis, Data Numbering Code: 2.13.3

PMRA Document Number: 1722994
Reference: 2009, Penta and Hexa chlorobenxene STD solution on GC, Data Numbering Code: 2.13.4

PMRA Document Number: 1722995
Reference: 2009, PDCB on GC showing no penta or hexa, Data Numbering Code: 2.13.4

Additional Information

PMRA Document Number: 1784302
Reference: IPCS INCHEM, 2009, 1,4-Dichlorobenzene ICSC: 0037, Data Numbering Code: 2.14.11,2.14.7,2.14.9

PMRA Document Number: 1784305
Reference: J.T. Baker, 2007, p-Dichlorobenzene - MSDS Number: D2224, Data Numbering Code: 2.14.13